

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: RONALD SHORE
ANTONELLI, TERRY, STOUT & KRAUS, LLP
1300 N. 17TH STREET
SUITE 1800
ARLINGTON, VA 22209

PCT **DOCKETED**
1/25/2012 mek

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 183-51081A00	Date of mailing (day/month/year) 20 JAN 2012
International application No. PCT/US2011/052475	International filing date (day/month/year) 21 September 2011
Applicant BIOQUEST PROSTHETICS	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 82 70

For more detailed instructions, see PCT Applicant's Guide, International Phase, paragraphs 9.004 – 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ **With regard to any protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:**
- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. Following the expiration of 30 months from the priority date, these comments will also be made available to the public.

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90bis.1 and 90bis.3).

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide, National Chapters*.

Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer <p style="text-align: center;">Blaine R. Copenheaver</p> PCT Helpdesk: 571-272-4300 Telephone No. PCT OSP: 571-272-7774
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

DOCKETED

1/25/2012 mcl

Applicant's or agent's file reference 183-51081A00	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US2011/052475	International filing date (day/month/year) 21 September 2011	(Earliest) Priority Date (day/month/year) 21 September 2010
Applicant BIOQUEST PROSTHETICS		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☐ Certain claims were found unsearchable (see Box No. II).

3. ☐ Unity of invention is lacking (see Box No. III).

4. With regard to the title,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

a. the figure of the drawings to be published with the abstract is Figure No. 38

☒ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2011/052475

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 2/66 (2011.01)

USPC - 623/52

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61F 2/66, 2/70 (2011.01)

USPC - 623/24, 49, 50, 52, 55, 56

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PatBase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2005/097008 A2 (TOWNSEND et al) 20 October 2005 (20.10.2005) entire document	1, 3-7, 9-17
Y		2, 8
X	US 5,593,456 A (MERLETTE) 14 January 1997 (14.01.1997) entire document	18-21
Y	US 1,502,593 A (SHRODES) 22 July 1924 (22.07.1924) entire document	2
Y	US 2007/0213841 A1 (TOWNSEND et al) 13 September 2007 (13.09.2007) entire document	8

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

27 December 2011

Date of mailing of the international search report

20 JAN 2012

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-3201

Authorized officer:

Blaine R. Copenheaver

PCT Helpdesk: 571-272-4300

PCT OSP: 571-272-7774

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: RONALD SHORE
ANTONELLI, TERRY, STOUT & KRAUS, LLP
1300 N. 17TH STREET
SUITE 1800
ARLINGTON, VA 22209

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year)

20 JAN 2012

Applicant's or agent's file reference
183-51081A00

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US2011/052475

International filing date (day/month/year)

21 September 2011

Priority date (day/month/year)

21 September 2010

International Patent Classification (IPC) or both national classification and IPC

IPC(8) - A61F 2/66 (2011.01)

USPC - 623/52

Applicant BIOQUEST PROSTHETICS

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Date of completion of this opinion

27 December 2011

Authorized officer:

Blaine R. Copenheaver

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2011/052475

Box No. I **Basis of this opinion**

1. With regard to the **language**, this opinion has been established on the basis of:
☒ the international application in the language in which it was filed.
☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:
 - a. (means)
☐ on paper
☐ in electronic form
 - b. (time)
☐ in the international application as filed
☐ together with the international application in electronic form
☐ subsequently to this Authority for the purposes of search
4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US2011/052475

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	2, 3, 6, 8, 14, 15, 19	YES
	Claims	1, 4, 5, 7, 9-13, 16-18, 20, 21	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-21	NO
Industrial applicability (IA)	Claims	1-21	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1, 4, 5, 7, 9-13, 16 and 17 lack novelty under PCT Article 33(2) as being anticipated by Townsend et al., (hereinafter Townsend). Regarding claim 1, Townsend (embodiment shown in Figs. 41 and 42) disclose a lower extremity prosthesis (124) comprising: a foot keel (165), an elongated resilient shank (126), and a leg attachment (133); wherein the shank extends upwardly forming an ankle joint area and a lower, prosthetic part of a leg above the ankle joint area by way of an anterior facing convexly curved portion (127; pg. 27, lines 29-31); wherein the shank includes multiple shank sections (126, 131, 132) which are unbounded (unbounded and spaced from one another at lower ends) in one or more portions with each other (Fig. 41), and wherein the shank sections incorporate at least one of voids (Figs. 41 and 42) between one or more shank sections (sections 126, 131, 132 are spaced or have voids between lower ends) to enhance shank flexibility while reducing stresses which can cause premature failure (pg. 28, lines 5-14).

Regarding claim 4, Townsend disclose wherein the multiple shank sections are spaced from one another in the sagittal direction intermediate upper and lower ends of the shank (pg. 27, line 30 and pg. 28, line 26).

Regarding claim 5, Townsend further disclose wherein the shank has a lower end (near 127) which is connected to the foot keel by way of a coupling element (129) and at least one fastener (fastener shown in Fig. 41).

Regarding claim 7, Townsend disclose wherein the shank has a lower end (near 127) connected directly to the foot keel by way of at least one fastener (fastener shown in Fig. 41).

Regarding claim 9, Townsend disclose wherein the shank has a lower end (near 127) which is connected to a posterior aspect of an upwardly arched midfoot portion of the foot keel (Fig. 41).

Regarding claim 10, Townsend disclose wherein the shank (126) has a substantially vertically oriented upper end (pg. 28, lines 5-7; Fig. 41).

Regarding claim 11, Townsend disclose wherein the shank has a substantially horizontally oriented lower end (pg. 27, line 31; Fig. 41).

Regarding claim 12, Townsend disclose wherein the radius of curvature of the anterior facing convexly curved portion (127) of the shank increases progressively as the shank extends upwardly (pg. 27, lines 29-32; Fig. 41).

Regarding claim 13, Townsend disclose wherein the shank in both the ankle joint area and the lower, prosthetic part of the leg above the ankle joint area is anterior facing convexly curved (pg. 27, lines 29-32; Fig. 41).

Regarding claim 16, Townsend further disclose wherein the multiple shank sections (126, 131, 132) extend in the longitudinal direction of the elongated resilient shank intermediate upper and lower ends of the shank (Fig. 41).

Regarding claim 17, Townsend (embodiment shown in Figs. 41 and 42) disclose a lower extremity prosthesis (124) comprising: a foot keel (165), an elongated resilient shank (126), and a leg attachment (133); wherein the shank has upper and lower ends (Fig. 41), the shank being connected at the lower end to the foot keel by way of a coupling element (129) and at least one fastener (fastener shown in Fig. 41) and extending upwardly forming an ankle joint area and a lower prosthetic part of a leg above the ankle joint area by way of an anterior facing convexly curved portion (127; pg. 27, lines 29-31); wherein the shank includes multiple shank sections (126, 131, 132) which are spaced from one another in the sagittal direction intermediate the upper and lower ends of the shank (sections 126, 131, 132 are spaced or have voids between lower ends; Fig. 41) and extending in the longitudinal direction of the elongated resilient shank to enhance flexibility while reducing stresses which can cause premature failure (pg. 28, lines 5-14).

(Continued In Supplemental Boxes)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US2011/052475

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box V

Claims 18, 20 and 21 lack novelty under PCT Article 33(2) as being anticipated by Merlette.

Regarding claim 18, Merlette disclose a method of making a resilient prosthetic component (10) comprising; the step of: monolithically (Abstract) forming a plurality of resilient elements (12, 14, 16, 24) utilizing at least a one part form, heat and pressure (col. 3, line 40 and 55), disassembling the formed, resilient elements (col. 3, lines 42-55), removing material (machining or molding of fastening holes) from an intermediate portion of at least one of the resilient elements (24) to form at least one gap, void or space therein, assembling the formed elements to form a resilient prosthetic component (col. 3, lines 58-67) wherein the gap, void or space therein reduces inter-laminar shear forces in the component (col. 3, line 58- col. 4, line 4).

Regarding claim 20, Merlette further disclose wherein the assembling includes connecting the resilient elements together at the ends of the component (col. 3, line 58 -col. 4, line 4).

Regarding claim 21, Merlette disclose wherein the prosthetic component is a resilient leg member for a lower extremity prosthesis (Abstract; col. 2, lines 55-60).

Claims 2 lacks an inventive step under PCT Article 33(3) as being obvious over Townsend et al., (hereinafter Townsend) in view of Shrodes.

Regarding claim 2, Townsend disclose wherein the multiple shank sections (126, 131, 132) are connected together at an upper end (pg. 28, lines 5-7; Fig. 41), but does not disclose the shank sections are connected together at lower ends of the shank.

Shrodes, however, teaches a prosthesis limb (Title) comprising a resilient shank (15) including multiple shank sections (15, 16) connected together at an upper end (near 10) and a lower end (near 12, 13; Fig. 1).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the prosthesis of Townsend to incorporate the prosthesis limb as taught by Shrodes, for the purpose of providing increased and resilient flexure of the keel or foot of a lower extremity prosthesis near trans-crucial ligaments, such that these ligament points resemble operation and construction of a normal human foot.

Claims 3, 6, 14 and 15 lack an inventive step under PCT Article 33(3) as being obvious over Townsend et al., (hereinafter Townsend).

Regarding claim 3, Townsend disclose wherein the multiple shank sections are respective sections (126, 131, 132), but not all of the sections are formed in an integrally formed shank.

However, the design of multiple shanks formed in an integral form structure is considered a matter of preference in the design of working structure, and well within the purview of a skilled artisan.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the prosthesis of Townsend to incorporate multiple shank section formed integrally, for the purpose of providing increased and resilient flexure of the keel or foot of a lower extremity prosthesis near trans-crucial ligaments, such that these ligament points resemble operation and construction of a normal human foot.

Regarding claim 6, Townsend does not disclose wherein a slot extends longitudinally through a posterior portion of the foot keel, the coupling element and a distal portion of the shank to bifurcate a portion of the prosthesis.

However, in an alternative embodiment shown in Figures 37 and 38, Townsend does illustrate a slot (113) extends longitudinally through a posterior portion of the foot keel (120; pg. 27, lines 10-15; Fig. 37), thus causing a coupling element and a distal portion of a shank to bifurcate a portion of the prosthesis (Figs. 37 and 38).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the prosthesis of Townsend to incorporate the foot keel shown in an alternative embodiment, for the purpose of efficiently transferring forces of user's center of gravity through the hindfoot of the foot keel for achieving normal stride of a user.

Regarding claim 14, Townsend does not specifically state in the preferred embodiment wherein the foot keel includes fore-, mid-, and hind foot portions, the fore-and hind foot portions being tapered in thickness at the ends and curved proximally, and the midfoot portion being upwardly arched, and wherein the midfoot portion incorporates at least one fastener on its posterior surface which attaches the shank.

However, in an alternative embodiment, of figures 3-5, Townsend illustrates a prosthesis (1), showing a foot keel (2) includes fore (3)-, mid (5)-, and hind (4) foot portions, the fore-and hind foot portions being tapered in thickness at the ends and curved proximally (Figs. 3-5), and the midfoot portion being upwardly arched (pg. 7, line 28), and wherein the midfoot portion incorporates at least one fastener (8) on its posterior surface which attaches to a shank (6; pg. 7, lines 24-33).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the prosthesis of Townsend to incorporate the foot keel shown in an alternative embodiment, for the purpose of efficiently transferring forces of user's center of gravity through the hindfoot of the foot keel for achieving normal stride of a user.

Regarding claim 15, Townsend does not, in the preferred embodiment, disclose wherein at least one of the foot keel and shank is partially bifurcated by the provision of a slot extending in the direction of the length thereof.

However, in an alternative embodiment shown in Figures 37 and 38, Townsend does illustrate a slot (113) extends longitudinally through a posterior portion of a foot keel (120; pg. 27, lines 10-15; Fig. 37), in the direction of the length thereof (Figs. 37 and 38).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the prosthesis of Townsend to incorporate the foot keel shown in an alternative embodiment, for the purpose of efficiently transferring forces of user's center of gravity through the hindfoot of the foot keel for achieving normal stride of a user.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US2011/052475

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Claims 8 lacks an inventive step under PCT Article 33(3) as being obvious over Townsend et al., (hereinafter Townsend) in view of US 2007/0213841 A1 to Townsend et al, (hereinafter Townsend 841).

Regarding claim 8, Townsend does not disclose wherein a stop is provided on the prosthesis for limiting anterior motion of the shank. However, Townsend 841, teaches a prosthetic foot (Abstract; Figs. 32-34) comprising a foot keel (101) and resilient shank (105), the prosthetic foot includes a stop (113) for limiting anterior motion of the shank (para. [133]).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the prosthesis of Townsend to incorporate the prosthetic foot as taught by Townsend 841, for the purpose of efficiently transferring forces of user's center of gravity through the hindfoot of the foot keel for achieving normal stride and balance of a user.

Claim 19 lack an inventive step under PCT Article 33(3) as being obvious over Merlette.

Regarding 19, Merlette does not specifically state that the material is removed by cutting.

However, Merlette states that the material forming the resilient element (24) is either machined or molded (col. 3, line 61) and typical techniques of either machining or molding and further to remove material to form holes or voids require cutting, laser cutting, milling or machining involves a process of removing material by a well known cutting technique.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the resilient prosthetic component of Merlette, such that the material of element 24 is removed by cutting, for the purpose of utilizing easy and accurate extracting techniques that keep cost minimal and overall functionality simple without stresses and cracks to the prosthesis during assembly.

Claims 1-22 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.